

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et.al.*,

Plaintiffs,

—v—

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 3:21-cv-00806-FLW-LHG

**AMERICAN HOSPITAL ASSOCIATION,
340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS,
ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
CHILDREN'S HOSPITAL ASSOCIATION, AND
AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS'
CONSENT MOTION TO FILE *AMICUS* BRIEF IN SUPPORT OF
DEFENDANTS**

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American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, National Association of Children's Hospitals d/b/a the Children's Hospital Association, and American Society of Health-System Pharmacists (collectively, the Proposed *Amici*) move this Court for leave to file the attached *amicus* brief in support of Defendants' opposition to Plaintiffs' cross-motion for summary judgment (Exhibit A). Proposed *Amici* also submit a Proposed Order (Exhibit B). Proposed *Amici* consulted with counsel for Plaintiff and Defendants. Plaintiffs have deferred taking a position on the Motion, and Defendants consent to the Motion.

Although the Federal Rules of Civil Procedure do not directly address the filing of *amicus* briefs, “[d]istrict courts have broad discretion to appoint amicus curiae.” *United States v. Farber*, No. 06-2683 (FLW), 2006 WL 2417272, at *1 (D.N.J. Aug. 21, 2006) (citation omitted). “[A] court may grant leave to appear amicus curiae if it deems the proffered information timely and useful,” and doing so “may be advisable where third parties can contribute to the court’s understanding.” *Id.* (citations omitted). Proposed *Amici*’s timely brief would aid the Court’s understanding by providing a unique perspective, insights, and specific information that the parties cannot otherwise provide. Additionally, if the Court were to grant Plaintiffs’ cross-motion for summary judgment, Proposed *Amici*’s members would be directly affected, further underlining the value of the *amicus* brief. See *United*

States v. Alkaabi, 223 F. Supp. 2d 583, 592 (D.N.J. 2002) (including whether “the *amicus* has a ‘special interest’ in the particular case” as consideration for granting *amicus* status).

Proposed *Amici* are six hospital/health system associations whose members use 340B discounts for 340B drugs dispensed through contract pharmacies to support health care programs and services offered by their hospitals. The discounts, for example, allow these members to (1) provide and maintain more patient care services; (2) provide and maintain more uncompensated and unreimbursed care; (3) provide and maintain more services in underserved areas; (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open. Am. Decl. of James W. Boyan III in Supp. of Proposed Intervenors’ Mot. to Intervene (Boyan Decl.), Ex. A (Decl. of Maureen Testoni in Supp. of Proposed Intervenors’ Mot. to Intervene (Testoni Decl.)) ¶¶ 7–9, ECF No. 29. These discounts are the subject of the Department of Health and Human Services (HHS) General Counsel’s December 30, 2020 Advisory Opinion¹ and a May 17, 2021 letter from the Acting Administrator of the Health Resources and Services Administration (HRSA),² which

¹ Boyan Decl., Ex. G (*Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020)).

² Letter from Diana Espinosa, Acting Administrator, HRSA, to Farruq Jafery, VP, Pricing, Contract Operations & Reimbursement, Novo Nordisk, Inc. (May 17, 2021), <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-entities.pdf>.

both concluded that the refusal by drug companies to provide 340B providers 340B discounts for drugs dispensed through contract pharmacies is unlawful, in violation of the 340B statute. Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, Novo Nordisk) challenge both the Advisory Opinion and the letter and urge the Court to decide on the merits what the statute requires of drug manufacturers. The Advisory Opinion has since been withdrawn. ECF No. 52.

Proposed *Amici* move for leave to file the attached brief (1) to assist the Court in assessing whether the 340B statute requires drug manufacturers to offer 340B discounts when drugs are dispensed by contract pharmacies; (2) to assist the Court in assessing Novo Nordisk's allegation that HHS has changed its position on the issue of contract pharmacies; (3) to assist the Court in assessing whether Novo Nordisk's alleged concerns about diversion and duplicate discounts provide legal support for its policy of refusing to provide discounts when 340B drugs are dispensed by contract pharmacies; and (4) to provide the Court with information regarding the impact of Novo Nordisk's policy on 340B covered entities such as Proposed *Amici*'s members. The proposed *amicus* brief provides the Court information not otherwise offered by the parties regarding 340B covered entities, contract pharmacy arrangements, and the 24-year history of covered entities using contract pharmacies as part of the 340B program and drug manufacturers, including Novo Nordisk, honoring those arrangements.

Indeed, since the beginning of the program, Novo Nordisk and all other major pharmaceutical companies provided 340B discounts for drugs dispensed through both in-house and contract pharmacies to covered entities' patients, and since 2010 they have sold drugs at the required 340B prices to hospitals and other covered entities who used multiple contract pharmacies. For 24 years, between 1996 and December 2020, there is no record that Novo Nordisk ever contested HHS's interpretation of section 340B as allowing 340B drugs to be dispensed by contract pharmacies. Today, a quarter of the benefit that 340B hospitals receive from the 340B discount comes from 340B drugs dispensed through contract pharmacy arrangements. For some the benefit is even higher, such as critical access hospitals (small hospitals in rural areas) that report that an average of 51% of their benefit from the 340B discount comes from drugs distributed through contract pharmacies. Boyan Decl., Ex. A (Testoni Decl.) ¶ 6. Yet Novo Nordisk now asks the Court to rule that it need not honor *any* contract pharmacy arrangements, a result that would harm Proposed *Amici*'s members, the patients they serve, and the public interest generally, particularly during the worst public health crisis in a century.

Proposed *Amici* respectfully request the Court to grant their motion to file an *amicus* brief.

Dated: June 22, 2021

Respectfully submitted,

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